# Cystic Fibrosis Gene Therapy

| Member and Medication Information (required) | |
|---|---|
| Member ID: | Member Name: |
| DOB: | Weight: |
| Medication Name/ Strength: | Dose: |
| Directions for use: | |

| Provider Information (required) | | |
|---|---|---|
| Name: | NPI: | Specialty: |
| Contact Person: | Office Phone: | Office Fax: |

**FAX FORM AND RELEVANT DOCUMENTATION INCLUDING: LABORATORY RESULTS, CHART NOTES and/or UPDATED LETTER OF MEDICAL NECESSITY TO 855-828-4992**

**Criteria for Approval (at least one of the following criteria must be met):**

- ❑ Medication is prescribed by or in consultation with a pulmonologist or pulmonary nurse practitioner.
- ❑ Patient is managed by a Cystic fibrosis clinic. Clinic Name: _____
  Details if not managed by a CF clinic: _____
- ❑ Patient is adherent to evidence-based inhaled and oral therapies for pulmonary cystic fibrosis.
- ❑ Baseline FEV1. Chart note page #: _____
- ❑ Include a copy of the CF mutation laboratory test.

**Additional Criteria for Kalydeco (ivacaftor):** ***Patient must be 4 months and older***

- ❑ List CFTR gene mutation. Chart note page #: _____

**Additional Criteria for Orkambi (lumacaftor-ivacaftor):** ***Patient must be 2 years and older***

- ❑ Laboratory Confirmed Cystic fibrosis, HOMOZYGOUS F508del mutation of the CFTR gene. Chart note page #: _____

**Additional Criteria for Symdeko (tezacaftor-ivacaftor):** ***Patient must be 6 years and older***

- ❑ Laboratory Confirmed Cystic fibrosis, HOMOZYGOUS F508del mutation of the CFTR gene. Chart note page #: _____
- ❑ List CFTR gene mutation. Chart note page #: _____

**Additional Criteria for Trikafta (ivacaftor-tezacaftor-elexacaftor):** ***Patient must be 6 years and older***

- ❑ Laboratory Confirmed Cystic fibrosis and at least one F508del mutation of the CFTR gene. Chart note page #: _____

**Re-authorization Criteria:**
Updated letter of medical necessity or updated chart notes demonstrating improved FEV1 from baseline.

**Initial Authorization:** Up to six (6) months
**Re-authorization:** Up to one (1) year

**Note:**

- ❖ Co-administrations with CYP3A inducers are not recommended.
- ❖ Hepatic function should be assessed by liver function lab test prior to initiating treatment, every 3 months during the first year of treatment, and annually thereafter.
- ❖ Cataracts: Baseline and follow-up examinations are recommended in pediatric patients initiating treatment.

**PROVIDER CERTIFICATION**

I hereby certify this treatment is indicated, necessary and meets the guidelines for use.

_____ _____
Prescriber's Signature Date